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An Evaluation of the Vitamin A Deficiency Prevention Pilot Project in Indonesia

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AMERICAN FOUNDATION
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c.)

FINAL REPORT

An Evaluation of the Vitamin A Deficiency Prevention Pilot Project in Indonesia 1973 - 1975

Evaluation Team

IGNATIUS TARWOTJO, M.S. - Principal Evaluator
S. GUNAWAN, M.D. - Clinical Investigator
STANLEY REEDY, M.D., M.P.H. - Principal Consultant
JOHANNA TEN DOESSCHATE, M.D. - Clinical Consultant
ELIZABETH HOUSE, M.P.H. - AFOB Field Representative
SUSAN T. PETTISS, Ph.D. - Planning Consultant

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Prof. Dr. Dradjat Prawiranegara, Chairman and Project Director
Dr. Slamet Santoso, Deputy Project Director
Mr. Moehartono, Secretary
Mr. Ignatius Tarwotjo, Principal Evaluator
Dr. Darwin Karyadi
Dr. Karthari, D.S.
Mr. Jumadias
Drs. Permadi
Mr. Soeprapto

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INTRODUCTION

In a number of countries where vitamin A deficiency is known to occur with some frequency, it is felt to be a leading cause of blindness among preschool age children.[1,2,3] Recognition of the magnitude of this blindness problem has been increasing for a number of years, along with an awareness of the enormous cost to society of childhood blindness and the possibility of its prevention.[4,5]

An extensive literature attests to the continuing interest in the biochemical and clinical aspects of vitamin A deficiency in relation to eye structures.[6,7] Although the exact pathways of damage caused by vitamin A deficiency remain to be elucidated, modern technology has enabled the continuing illumination of biochemical and physiological processes. But in spite of this progress, blinding disease due to vitamin A deficiency has persisted into the modern era. As pointedly stated by O.A. Roels at an International Symposium on Metabolic Functions of Vitamin A held in 1968, "Once again, the very great incidence of vitamin A deficiency throughout the world was stressed. In view of the serious consequences of vitamin A deficiency, e.g., blindness and death in children...it is very surprising that although we have been able to investigate many aspects of the metabolic function of vitamin A and we have been able to synthesize and produce vitamin A at low cost, we have failed to tackle the public health problem and eradicate this dreadful disease."[8]

The global survey completed by Oomen, Escapini and McLaren in 1964[9] brought to a focus the growing international concern. A succession of international meetings, including the Symposium referred to above, has brought together experts and organizations in the field. Low cost production of synthetic vitamin A has stimulated interest in mass distribution and fortification schemes.

The meeting in Hyderabad in 1972[10] on Prevention of Xerophthalmia in South-East Asia heard reports on the effectiveness of biannual administration of capsules containing 200,000 IU of vitamin A in reducing the incidence of conjunctival signs of xerophthalmia in preschool children. As a result, pilot or nationwide programs have been planned or initiated in India, Indonesia, Bangladesh, El Salvador, and the Philippines; preliminary reports on these activities are becomming available.[11-15] This report hopes to contribute to the prevention effort by presenting the experience of Indonesia's pilot program.

BACKGROUND

Indonesia is a country of many islands, with an estimated population in 1974 of 129.5 million. The pilot project was carried out on Java, the most heavily populated island. The population density of Java averages 1500 per square mile. The crude rate of natural increase is 2.4% per year. Infant mortality is estimated to be 115-140 per thousand live births; approximately 20% of children die before reaching age 20, mainly due to respiratory and gastrointestinal disease. Life expectancy at birth is 44-48 years.

The per capita GNP is approximately US $100. In spite of

intensive efforts at development, food self-sufficiency has not yet been achieved. Literacy is 45% among a population that is 83% rural; 70% of the labor force is in agriculture. In general, electricity is not available in smaller towns and rural areas. Except in the very largest cities, sanitary sewage and water services are non-existent. Health services at the local level are poorly utilized. The overall doctor to population ratio is 1:20,000 and considerably less in rural areas.

Xerophthalmia has received attention in Indonesia for many decades, from many investigators.[16] The sex differential, with males experiencing more xerophthalmia than females, and the relationships with poverty and malnutrition were noted early. Serum studies on vitamin A and carotene have been inconclusive except in cases of keratomalacia. The extensive reports of Oomen on malnutrition and xerophthalmia provided impetus to postwar investigations that have increased the store of epidemiologic knowledge.[2,18] Oomen deserves credit for persistently focusing attention on a condition whose sufferers often die from related malnutrition or remain secluded due to blindness, thus obscuring the true public health weight of the problem.[7,17]

The Ministry of Health has given high priority to the prevention of vitamin A deficiency in children, and has expressed in the 1974-1979 Five Year Plan its commitment to provide preventive measures. The concurrent preoccupation of the post-1967 government with economic development has led to a more intense look at the ways in which improved health and nutrition, particularly for the

young who represent the nation's future citizenry, might pay off both in reduced health expenses and in increased individual productivity.

The Nutrition Institute of the Ministry of Health in Indonesia had given attention to the problem of vitamin A over a long period of time. Personnel from this institution contributed to the preliminary report presented in Hyderabad regarding the results of massive-dose prophylaxis. It was felt that in light of the apparently increasing incidence of xerophthalmia and keratomalacia, short-term emergency measures were required. Since massive dose prophylaxis makes considerable demands on personnel and finances, it was decided that a careful pilot study was required.

A committee was appointed to draw up plans for a pilot project. The American Foundation for Overseas Blind (AFOB) offered to assist with an evaluation of this pilot effort. A plan was formulated with two major components. One component was a clinical study designed to determine the biological effectiveness of the vitamin A capsules in preventing xerophthalmia in a field operation. The second component was an assessment of the capsule distribution system. The results from these two project components are intended as input to the decision-making process in the program area of vitamin A deficiency prevention. The following is a final report on the evaluation of this project.

SECTION I - CLINICAL STUDY

A. OBJECTIVE

The objective of the clinical study was to determine the effectiveness, in preschool children, of biannual administration of

capsules containing 200,000 IU of vitamin A and 40 IU of vitamin E in oily suspension, in preventing the appearance of clinical eye signs of vitamin A deficiency (xerophthalmia).

B. STUDY AREA

Indonesia, located in the tropics, presents a wide variety of ecological situations due to differing rainfall, soil fertility, crop choice, population pressure on the land, and a host of other variables. In light of this variety, it was decided that the clinical study area should, first of all, be an area where xerophthalmia is known to occur with some frequency, according to the records of government clinics. A further criterion was the availability of adequate personnel, particularly ophthalmologists.

The area chosen for the study is in the upland plateau area of Central Java, approximately 50 km. inland from the provincial capital, Semarang. Seven urban and five contiguous rural villages with population adequate to meet the sample requirements were chosen. The study villages were of average to low economic status, since xerophthalmia is known to occur rarely in areas of general affluence. The study villages were generally representative of the area in regard to availability of educational, medical, and commercial facilities, and types of home construction. The urban villages, in the city of Salatiga, were more uniform than the rural villages regarding source of water supply, method of sewage disposal, and distance from major roads and rivers. The rural villages also displayed variation in the proportions of rice, corn, and cassava grown and eaten. Urban and rural villages shared the same climatic influences, with the rainy season usually occurring from November to March, and the drier months from June through October.

C. STUDY POPULATION

1. Sample Size:

The sample population consisted of 2,812 children, 1,409 males and 1,403 females, in the age range 12-60 months. One thousand four hundred and thirty eight children in the sample population were in the urban area and 1,374 in the rural area. The calculation of sample size was based on an estimate of 7.0% prevalence of xerophthalmia and on a projected 50-70% reduction of prevalence of conjunctival signs in the experimental group. The sample was inflated to allow for mortality, emigration, and non-cooperation. All children aged 12-60 months in the seven urban and five rural study villages were registered.

2. Completeness of Registration:

The initial census and registration was incomplete due to use of existing census lists rather than a house-to-house search using maps of the area. Two estimates of under-registration are available. A repeat census was performed in the clinical study area itself, covering one rural and one urban village; an estimated 11.3% of eligible children had been missed according to this count. A repeat census conducted as a part of the evaluation of the capsule distribution system component of the pilot project resulted in an estimate of 10% for the proportion of eligible children who were missed.

Difficulties in age estimation at the upper age limit, combined with a possible desire by parents to obtain benefits for children actually past the age limit may have acted to increase the apparently missed percentage found on the repeat censuses.

Table I, which portrays the age distribution of the children who were examined, indicates the disproportionately low number in the highest age group, suggesting that the latter effect was not an influence at the time of the baseline examination. It is possible that the children who were missed were more likely to be poorer, severely ill, or more malnourished than those who entered the study, and thus at higher risk of xerophthalmia. If this is the case, the study prevalence figure understates the size of the group with and at risk of xerophthalmia.

3. Age:

The age distribution of the 2,812 children examined at the baseline examination is shown in Table I. Although in general there is less variation with age in the rural area, the entire distribution illustrates the general problem of attribution of age in a situation where complete birth registration and parental knowledge of exact age is not yet common. Because there is no consistent pattern through the various villages, it is difficult to make any analytic comment; the grand totals indicate a heaping up of values in the two middle age ranges. This may represent age attribution error in opposite directions at the two extremes; that is, withholding of younger infants from the study simultaneous with higher likelihood of absence from the home for those near five years of age. Although exact age attribution would have been useful, resulting in greater confidence in statements about prevalence and incidence at different ages, the lack of it does not significantly affect the results obtained once the children have been assigned to experimental and control groups.

TABLE I

AGE DISTRIBUTION OF THE SAMPLE 2,812 CHILDREN

	AGE (MONTHS)			
	12-23	24-35	36-47	48-60
Urban	323	420	421	274
Rural	344	312	327	391
Total	667	732	748	665

4. Sex:

The distribution of the 2,812 children according to sex and place of residence demonstrated little variation with an insignificant difference in the grand totals.

D. STUDY DESIGN AND PROCEDURES

Seven urban and five rural villages were chosen, and all children aged 12-60 months in those villages were registered. The original study design called for all registered children to receive a baseline ophthalmologic examination. Children found to have xerophthalmia were to be treated and excluded from the experimental and control groups. The remaining children were to be numbered consecutively as they appeared for examination and systematically assigned to experimental and control groups, based on their odd or even numbers. The ophthalmologic examinations were to be repeated at 12 and 24 months after the baseline examinations, with Vitamin A and placebo administration repeated every 6 months.

In the design actually implemented, however, ophthalmologic examinations were performed at 6 and 12 months after the baseline, simultaneous with Vitamin A and placebo administration. This was thought necessary because the baseline prevalence of xero-

phthalmia was found to be considerably lower than the pre-study estimate. Excessive dropout over the two year span of the study might have eliminated the possibility of statistically significant measurements. It was also thought that biannual examination might reveal seasonal variation that would be obscured by repeat examinations during the same season each year. The study began with the baseline examinations in July and August, 1973. The second round of examinations was in February and March, 1974, and the final round was conducted in September and October, 1974.

There were two examining teams in the field; one worked only in the rural area, and the other only in the urban area. Each team consisted of an ophthalmologist, a trained eye nurse, and auxiliary personnel for the tasks of record-keeping, administration of capsules, collection of children, and arrangement of home visits. Home visits were occasionally required to locate and examine ill or missing children. The ophthalmologists were not available for the 12 months examinations, which were performed by the two experienced eye nurses, who had participated in the previous rounds of examinations.

The examiner examined the anterior segment of both eyes of each child and recorded the findings on specially designed forms. The criteria used for definition of a case were derived from the classification of ten Doesschate. Definition of a case was the occurrence in one or both eyes of xerosis of the conjunctivae and/or cornea, Bitot's spots, dryness, wrinkling, and thickening of the bulbar conjunctivae, and corneal scarring or active corneal disease that was, in the opinion of the examiner, related to current or past hypovitaminosis A. Night blindness was noted, if described by the

child's caretaker, but tests for dark adaptation were not done. The examiners and the Clinical Consultant worked together to standardize diagnostic definition and recognition during each examination round. Night blindness as a diagnostic criteria was dropped after the baseline examination; it was rarely found alone, and was too subjective to be a useful finding.

The findings from each examination were recorded by the examiner. The data forms initially provided for the noting of a wide variety of eye changes other than those noted above. Following the baseline examination, the data forms were abbreviated by the deletion of unused and unnecessary items. Records were also kept regarding loss to followup due to mortality, emigration, and noncooperation. Eligible children missed by the original registration and baseline examination, but found on subsequent rounds, were examined but were not included in the study population.

All xerophthalmia patients identified were given Vitamin A capsules and examined on subsequent rounds for persistence or disappearance of the lesions first noted. In each case of xerophthalmia there was an attempt to obtain a medical history as to recent or chronic illness, or unusual dietary factors. No food supplements were given, and nutrition education was specifically avoided during the study period. Local health practitioners were requested not to administer Vitamin A during the study period, except to children with eye lesions felt to be clearly xerophthalmic.

The gelatin capsules administered to the study population contained either 200,000 IU of vitamin A with 40 IU of vitamin E in oily suspension, or an identically flavored and colored placebo.

The administration of capsules was carried out on a double-blind basis, with the code for identification of the vitamin and placebo recipients held by the Principal Evaluator in Jakarta. A complete description of study procedures is provided in the study protocols.

E. RESULTS

1. Baseline Point Prevalence of Xerophthalmia:

Tables II and III present the prevalence rates of xerophthalmia found at the baseline examinations, by place of residence, sex, and age group. The overall prevalence estimate of 4.7% is considerably less than the preliminary estimate of 7.0% used for calculating sample size. There is a strong overall male/female differential, 6.0% to 3.4%. There is no significant difference between urban and rural rates, even when held constant for sex. As shown in Table III, the prevalence rate in both urban and rural areas rises steadily with increasing age.

TABLE II

BASELINE PREVALENCE OF XEROPHTHALMIA (%) BY SEX

	MALE	FEMALE	TOTAL
Urban	5.1	3.4	4.3
Rural	6.8	3.5	5.2
Total	6.0	3.4	4.7

TABLE III

BASELINE PREVALENCE OF XEROPHTHALMIA (%) BY RESIDENCE AND AGE

	AGE (MONTHS)			
	12-23	24-35	36-47	48-60
Urban	0.3	3.6	5.7	7.2
Rural	0.9	2.9	7.9	8.4
Total	0.6	3.3	6.7	8.1

2. Baseline Occurrence of Specific Signs in Xerophthalmia:

Table IV presents the frequency of occurrence of several eye signs among children found to have xerophthalmia. The prevalence of Bitot's spots, considered to be a specific sign for xerophthalmia in Indonesia, was 4.2% in the population examined. Table IV reflects the fact that the diagnosis in most cases rested on the presence of Bitot's spots. Attempts were made to evaluate reports of night blindness, but due to its subjective nature it was not useful in diagnosis. Conjunctival injection and pigmentation were infrequently found, in association with the other signs.

TABLE IV

EYE SIGNS FOUND IN XEROPHTHALMIA CASES, BASELINE EXAMINATION

	RURAL n=71	URBAN n=61	TOTAL n=132
Conjunctival dryness, wrinkling, or thickening, or in combination	71	15	86
Bitot's spots	66	53	119
Conjunctival injection	5	5	10

(Note: Cases had one or more of these findings, except that conjunctival injection alone was not adequate to define a case.)

3. Six Months Examination:

The children were examined six months after the baseline in the same order as in the baseline examination, by the same ophthalmologists. Strenuous efforts were made to collect all children previously examined, with particular emphasis on previously identified and treated xerophthalmic cases.

4. New Cases of Xerophthalmia:

The experimental and control groups yielded proportions of new cases after six months that were significantly different according to statistical testing. The overall point prevalence after six months among those examined was, for the experimental group, 0.4%, and for the control group, 3.6%.

TABLE V

SIX MONTHS EXAMINATION:

TOTAL CASES OF XEROPHTHALMIA BY STUDY GROUP AND PLACE OF RESIDENCE

		EXPERIMENTAL n=1286	CONTROL n=1183	TOTAL n=2469
Urban	n=1222	2	16	18
Rural	n=1247	4	27	31
	Total	6	43	49
Point Prevalence		0.4%	3.6%	

One case in the experimental group was dropped because of incomplete recording of data. Even with this case included, the difference between rates for experimental and control is statistically significant. Table V shows a differential between urban and rural children which appears strong but which is not in fact statistically significant.

Tables VI and VII portray other aspects of the xero-

phthalmia cases identified at six months. Table VI indicates that after cases were removed at the baseline examination, new cases developed primarily in the younger age groups, both in experimental and control groups.

TABLE VI

SIX MONTHS EXAMINATION:

TOTAL CASES OF XEROPHTHALMIA BY AGE AND STUDY GROUP

Age (months)	EXPERIMENTAL	CONTROL	TOTAL
12-23	2	10	12
24-35	1	13	14
36-47	3	14	17
48-60	0	6	6
Total	6	43	49

The strong sex differential that was evident at the baseline examination continues at six months.

TABLE VII

SIX MONTHS EXAMINATION:

TOTAL CASES OF XEROPHTHALMIA BY SEX AND STUDY GROUP

	MALE	FEMALE	TOTAL
Experimental	4	2	6
Control	27	16	43
Total	31	18	49

The specific eye signs found in new cases indicated no significant difference according to sex or place of residence. Night blindness was mentioned infrequently among children with

other eye signs. Pigmentation was noted rarely and continued to make an unimportant contribution to diagnosis. There is a strong correlation between the conjunctival signs of dryness, wrinkling, and thickening, and the presence of Bitot's spots. Only 2 of 47 children with Bitot's spots did not also demonstrate the other conjunctival signs. Of the 46 children with the group of conjunctival signs, only one did not have Bitot's spots. None of the 46 had a Bitot's spot on only one eye.

The seven cases of night blindness, which were spontaneously described by the parent, were all in the control group. The frequency of conjunctival injection was significantly higher than at the baseline examination, appeared in both experimental and control goups, and was also increased in both urban and rural areas. Conjunctival injection is not a recognized sign of xerophthalmia but it is more likely related to seasonal or sporadic conjunctivitis.

5. Loss to Follow-up:

Of 2,680 children who entered a study group at the time of the baseline examination, 211, or 7.9%, were lost to follow-up during the first six months. Loss to follow-up was not significantly different between experimental and control groups.

At the end of the second six month period, 6.1% of those children still eligible for examination were lost to follow-up. The overall loss to follow-up during the study was 9.7%. As would be expected, mortality was evenly divided among the study groups, and was consistent with known levels of child mortality in Central Java, suggesting that reporting

of deaths was good. Levels of migration and noncooperation were higher in the urban than in the rural area. This was consistent with known patterns of urban mobility, and the usual difficulty in recruitment for any type of study in urban areas. There was no significant sex differential for any of the three categories of loss to follow-up.

6. Response of Xerophthalmia Cases to Vitamin A Therapy:

Although the children in the study were not under continuous surveillance (due to lack of personnel and money for this task), a rigorous effort was made at the time of the six months examination to re-examine all children identified during the baseline examination as xerophthalmia cases.

TABLE VIII

SIX MONTHS EXAMINATION:

RESPONSE OF BASELINE XEROPHTHALMIA CASES TO VITAMIN A

	URBAN	RURAL	TOTAL
Total Cases	61	71	132
Re-examined	57	61	118
Recovered	49	58	107
Per cent of those re-examined who had recovered	86%	95%	91%

Ninety per cent of those cases were re-examined; of those, 91% were considered to be recovered, i.e., they did not exhibit signs of xerophthalmia. Because of the time lapse between administration of the Vitamin A capsule and later examination, it is not possible to conclusively attribute the disappearance of the eye signs solely to the vitamin that was

given, since intervening change in nutritional intake may have occurred. However, it is clear that almost all of the lesions noted had been reversed.

Because the ophthalmologists were not available, the senior eye nurses, under the supervision of the Clinical Consultant, performed the third round of examinations. The definition of a case was changed to only those children with Bitot's spots and/or corneal signs.

The findings again demonstrated a significant difference between groups, with a six month incidence of 2.9% in the control group and only 0.3% in the experimental group.

TABLE IX

TWELVE MONTHS EXAMINATION: TOTAL CASES OF XEROPHTHALMIA (BITOT'S SPOTS) BY STUDY GROUP AND PLACE OF RESIDENCE

		EXPERIMENTAL n=1197	CONTROL n=1072	TOTAL n=2269
Urban	n=1107	0	16	16
Rural	n=1162	3	15	18
Total	n=2269	3	31	34
Point Prevalence		0.25%	2.89%	

TABLE X

TWELVE MONTHS EXAMINATION:

TOTAL CASES OF XEROPHTHALMIA BY AGE AND STUDY GROUP

Age (months)	EXPERIMENTAL	CONTROL	TOTAL
12-23	0	5	5
24-35	1	10	11
36-47	0	9	9
48-60	2	7	9
Total	3	31	34

TABLE XI

TWELVE MONTHS EXAMINATION:

TOTAL CASES OF XEROPHTHALMIA BY SEX AND STUDY GROUP

	MALE	FEMALE	TOTAL
Experimental	1	2	3
Control	17	14	31
Total	18	16	34

F. Discussion

1. Methodological Limitations:

The study did not focus on the occurrence of keratomalacia, the acute, blinding form of Vitamin A deficiency (in which factors other than Vitamin A may yet prove to be equally or more important). This was largely due to the fact that intensive surveillance was not possible. Keratomalacia by definition is an acute condition which swiftly reaches a conclusion, and thus would rarely be detected by a study whose design consisted of repeated examinations of the entire sample population at six month intervals. Without a strong and widespread system of referral to hospital, determination of the actual incidence of keratomalacia in a population is exceedingly difficult.

It is not feasible to test large numbers of preschool children for dark adaptation. The study also did not attempt to demonstrate changes in the serum or liver levels of Vitamin A in its various metabolic forms, nor to measure the length of time that such changes required, nor how long they were sustained.

Studies based on observation of changes in serum and

liver values of Vitamin A, its metabolites, or carotene substances, and their relationships to clinical eye signs, would seem to be on solid ground. In practice, the serum and tissue kinetics of protein and Vitamin A compounds remain to be fully elucidated. It is hoped that an easily detected marker of actual or incipient Vitamin A deficiency will become known in the future so that the population at risk can be more sharply and easily defined. A low or non-existent level of Vitamin A is common in severe malnutrition with xerophthalmia, but usually serves only as confirmation of the clinical impression. Very low levels are probably predictive of a vulnerability to development of anterior segment eye signs and/or corneal damage. The use of serum and liver values is not practical at present, as noted earlier, for screening large populations in field situations.

2. Prevalence Rate:

The 4.7% overall prevalence rate of xerophthalmia found in the baseline examination was unexpectedly low. There are few field prevalence estimates for xerophthalmia in Indonesia. The high 17% figure found by Karyadi et al., in West Java near Bogor probably represents a selected population or reflects high endemicity due to strongly localized factors. The true prevalence of xerophthalmia in the study population is almost certainly slightly higher than the study finding of 4.7% since very sick and chronically ill children, who are most at risk, are also more likely to have not entered the study. Only two cases of corneal disease, both with scars, were found that could be reasonably attributed to Vitamin A deficiency.

The development of better medical reporting of xerophthalmia, and of simple techniques for determination of prevalence, will be of great value in planning the strategy for control of Vitamin A deficiency. Reliance on the trends of hospital and clinic data in the near future will remain as dubious as it has been in the past, due to the poor utilization of such facilities, and the inability of most medical personnel to accurately diagnose the condition. Too many factors still intervene to determine the attendance and non-attendance of sick children in clinics and hospitals, no matter how close the latter are to the patients' homes or how liberal the financial policies. Traditional healers and multiple other sources of health care exist in the community and preempt the confidence of the population. Fatalism, fear, and protection of sick children from the possible pain of therapy all operate to make attendance statistics difficult to interpret.

3. New Xerophthalmia Cases:

How long does it take for new cases to appear after children with signs of xerophthalmia are removed from the study population? The data cannot answer this, but Table X indicates that the appearance of new cases is more frequent in the younger age groups. Perhaps this illustrates a relative chronicity, at least in certain children, of the eye signs included in xerophthalmia. Such a chronicity would produce an upward bias in the prevalence rate because of a cumulative effect of what may be usually a non-progressive disease.

Of considerable significance for preventive programs

is the apparently easily reversible nature of xerophthalmia in this population. Although 91% of those found, treated, and then examined at six months were cured of their clinical disease, as noted earlier, this cannot be exclusively attributed to the treatment. The findings from India of Sinha and Bang[19] in the only prolonged surveillance study yet done suggest that the signs of xerophthalmia are rapidly reversible even without Vitamin A therapy. However, the report does not state whether therapeutic dietary measures had been advised for the xerophthalmic children, and it also does not give a breakdown of the cases that responded without therapy, i.e., whether those whose signs reversed were night blind or had Bitot's spots or other signs. The report does suggest a relationship with seasonal variation in diet.

The problem remains of determining exactly which children are most at risk of eye damage. It is clear that if the situation would permit, continued surveillance would probably yield considerably more descriptive and epidemiologic information about xerophthalmia. Repeated surveys at intervals cannot be expected to detect xerophthalmia that occurs and regresses during the interval, a pattern which is clearly suggested by the India data of Sinha and Bang referred to above.

4. Effectiveness of Prevention:

The striking difference between experimental and control group prevalence of xerophthalmia after six months provides strong confirmation of the effectiveness of the preventive regimen. The fact that cases still occurred in the experimental group suggests that the effect of the vitamin is relative and

not absolute. The vitamin's effects can be hindered in a number of ways. Because of the toxicity of large doses of Vitamin A, it is not feasible to go above a certain dose level in capsules intended for children. The amount given may not in fact be adequate for the body needs of all for the full six months. In a small proportion of children there may be failure to adequately absorb or retain the vitamin. Other children may experience unusual requirements for the vitamin because of the stress of disease or rapid growth. Generalized malnutrition may act to reduce the effectiveness of the large dose. And as part of the disease process of xerophthalmia and keratomalacia there may be specific local eye factors that are activated by an as yet unknown agent in the presence of low but otherwise adequate levels of serum and tissue Vitamin A.

5. Signs of Xerophthalmia:

One of the major problems in a field study on Vitamin A deficiency relates to the controversy over the usefulness of clinical eye signs. Active keratomalacia, or corneal scars with confirmatory history cause little difficulty in diagnosis. The specificity of Bitot's spots and other conjunctival signs is another matter. As with many biological phenomena, the etiology of Bitot's spots is obscure, their detection is somewhat subjective, and their relationship with other eye signs and physiological parameters is open to question. Since their original description, a train of subsequent descriptions and observations has followed. Findings vary widely; some investigators can ablate Bitot's spots with Vitamin A therapy, while others find them to be completely refractory to Vitamin A.

The present study was guided by the descriptions and conclusions accompanying the only known set of eye photographs correlated with serum and liver Vitamin A values.[20] That article noted that "Bitot's spot is a useful indicator of Vitamin A deficiency, especially in children, but it is not pathognomonic." In the preschool group, Bitot's spots and conjunctival signs are rather easily recognized.

It is clear that everywhere that xerophthalmia and keratomalacia are reported, the susceptible group is preschool children. Therefore, conclusions based on findings in school and adult populations are largely irrelevant. Geographic and racial differences may account for the differences in findings, or at least sufficiently so as to produce great caution in generalizing beyond the population under observation.

In terms of prevention of the ultimate blinding disease, keratomalacia, it is important to note that children with keratomalacia usually have conjunctival and corneal xerosis, and on occasion Bitot's spots as well. An important assumption for this study was that children with these conjunctival and corneal signs are therefore at higher risk than those without those signs, of future development of keratomalacia, either through the intervention of acute or chronic disease or some other mechanism. What is needed to reinforce and validate that assumption is a clearer definition of the relationships between the known eye signs in the spectrum preceding keratomalacia, in particular the transition probabilities from one "stage" to another, and their correlation with other perhaps more easily observable signs or measurement.

6. Seasonality as a Variable:

An assessment of a preventive measure such as distribution of massive dose capsules needs to consider the effect of a potential periodic variation in incidence of the eye signs and/or actual hypovitaminosis A. Although xerophthalmia is apparently endemic in a number of areas of Indonesia (at least where records are available) there is a strong suggestion from hospital and clinic records of xerophthalmia that incidence peaks in certain seasons, in relation to other precipitating or causative factors which have not been fully identified. This would not be expected to affect the validity of a double blind study utilizing a placebo, however.

Although seasonal peaks in June-August have been described for both Surabaya and Bandung,[21] a breakdown of the Surabaya cases indicated that the level of more severe corneal stages remained constant. A large variation in the occurrence of conjunctival stages produced the seasonal variation noted in the overall xerophthalmia figures. If it could be determined that subsequent keratomalacia patients came primarily from that peak load of xerophthalmia patients, the distribution of Vitamin A might be particularly timed just before the seasonal peak of xerophthalmia. But if the incidence of keratomalacia remains constant throughout the year, as seems to be the case in Surabaya, then there would be little virtue in a focused, once a year, "correctly timed" distribution. Further study and clarification is obviously in order.

This study found a prevalence of xerophthalmia of 4.7%

in July and August, the months which are thought to usually be the peak season for xerophthalmia in the study area. The repeat examination six months later, in February and March, with earlier cases removed, yielded a point prevalence rate of 2.0%. This change may be related to the alleged seasonal effect, or may be due to the time required to build up a population of children with the eye signs of xerophthalmia. Unfortunately, the length of time that such eye signs may be present without progression or regression is not known. No attempt was made to determine the time when the lesions were first noted by a parent, because of obvious difficulty in reliability.

The only longitudinal study that has been done with observations for xerophthalmia in children[19] suggests that the regular seasonal variation in the rate of growth of children may itself produce the seasonality in occurrence of xerophthalmia. Further analysis of the India data may clarify these factors. It will also be interesting to see if children with xerophthalmia which regresses are later subject to eye disease or higher than normal rates of infectious disease and/or mortality.

7. <u>Childhood Blindness and Survival</u>:

No cases of blindness, new or old, were found during the study. However, it is important to acknowledge the high mortality of blind children, as recorded in the works of both ten Doesschate and McLaren.[22] Survivorship is a major factor in the observation of numbers of blind children. Without continued surveillance, the occurrence of such events as keratomalacia oc-

curring shortly before death can easily be missed. Similarly, the prevention of such events cannot be documented.

G. MAJOR FINDINGS AND CONCLUSIONS

1. In the preschool age population studied, the administration of a dose of 200,000 IU of Vitamin A resulted in a six month incidence of xerophthalmia of 0.4%, compared with 3.6% in the control group.
2. The male/female differential previously noted in clinic and hospital patients was confirmed in the field.
3. Xerophthalmia signs were easily reversible.
4. No cases of blindness were found.
5. The findings in this study do not allow definite conclusions regarding seasonality.
6. After cases of xerophthalmia are removed, new cases appear more frequently in the lower age groups, suggesting the possibility of accumulation of non-progressive lesions as young children age.
7. There is a need for further intensive study of xerophthalmia and keratomalacia in the field, in order to identify causal factors and more sharply define the population at greatest risk.

H. SUMMARY

This evaluation is in relation to a specific dose, vehicle, distribution arrangement, time interval, and target age group. For that reason, it is not possible to make comments about various other possible combinations of these elements, except perhaps to encourage their testing. The demonstration of biologic effective-

ness does not obviate the necessity for evaluation of alternatives and careful analysis of costs and benefits for the planning of preventive programs. In particular, better ways of defining the population at highest risk should be sought.

SECTION II - ASSESSMENT OF DELIVERY SYSTEM

A. OBJECTIVE

The primary objective of the evaluation was to assess the the effectiveness and efficiency of the project operations in administering semi-annual dosages on a universal basis of vitamin A to the target population of preschool children in selected areas. Effectiveness was defined in terms of the proportion of the target population dosed during each distribution cycle. Efficiency was measured in terms of the number of capsules administered per worker/day, and in terms of cost per capsule administered. The evaluators would have preferred to have measured effectiveness and efficiency in terms of blindness prevented. However, present state of knowledge concerning the prevalence of xerophthalmia and the probilility of any given case of xerophthalmia developing into keratomalacia precludes analysis at that level of sophistication.

A secondary objective of the evaluation was to monitor project operations in order to obtain information about variables which affected effectiveness and efficiency. The feedback so obtained enabled adjustments to be made while the distribution was in progress, and should prove useful for the planning for expansion or for similar systems.

B. MASS DISTRIBUTION SYSTEM

1. Administrative Organization:

The distribution was planned and directed by the Vitamin

A Deficiency Prevention Pilot Project Committee of the Ministry of health. Prof. Dradjat Prawinegara served as Chairman of the Committee and Project Director. Dr. Slamet Santoso, as Deputy Project Director, held primary responsibility for the administration of the distribution. Responsibility for administration of project operations in each province was delegated to a Provincial Project Leader, assisted by a Provincial Project Committee.

From the provincial level administrative authority was delegated to the kabupaten physicians (Dokabu). Under the Dokabus responsibility was assigned to the 13 physicians who supervised the project field workers.

A schematic presentation of the administrative structure is shown in Appendix I.

2. Project Areas:

Selection of the geographical sites for the distribution was made by the project committee in each of the three provinces of Java. The principle criteria on which selection was based were:

a. high incidence of xerophthalmia as indicated by clinic and hospital records

b. availability of health workers to serve as project field staff

A total of twenty subdistricts (kecamatans) were selected. In West Java two rural subdistricts were chosen in Sumedang Regency and two rural subdistricts in Karawang Regency. The project areas in Central Java consisted of eleven rural subdistricts in Semarang

Regency. Three rural subdistricts in Lamongan Regency and two urban subdistricts in the municipality of Surabaya were selected in East Java.

3. Target Population:

Clinical records and field surveys have indicated that on the island of Java the highest incidence of ocular lesions related to vitamin A deficiency occurs in the age interval 12 to 48 months. This interval was therefore designated as the target age group for the pilot distribution.

The Project Protocol of September 1972 specified that the target population would consist of all children aged 12 to 48 months living in all of the villages in the twenty selected subdistricts. In West and Central Java these specifications were followed and the distribution was carried out according to plan.

In East Java a misinterpretation of the protocol resulted in limitation of the distribution to approximately a quarter of the villages in each of the five selected subdistricts. This departure from the protocol became known to the project administrators in Jakarta toward the end of the first distribution cycle. It was then decided to restrict subsequent distribution of capsules to those villages which had received capsules during the first distribution cycle.

For the purposes of the evaluation, estimates were made of the size of the target population in each of the twenty subdistricts. These estimates were based on adjusted population figures from the 1971 Population Census. Two estimates were made

for each subdistrict: A minimum estimate, which assumed no undercounting of children in the age interval 12 to 48 months in the 1971 census; and a maximum estimate, which assumed that the age interval had been undercounted by 10%. The two estimates span an interval within which the actual size of the target population is expected to lie.

A more detailed explanation of the target population estimates and their derivation is presented in Appendix II.

The total target population in the twenty subdistricts was estimated by the methodology described in Appendix II to number between 92,250 and 103,400 children. The Project Protocol had projected a target population of ± 200,000 children, and preliminary estimates of the target population in the twenty subdistricts had been approximately 189,000. The later estimates yielded a figure roughly half as large as the earlier estimates. This discrepancy seems to be attributable to two factors:

a. The elimination of approximately 23,000 children from the target population by the reduction of the project areas in East Java; and

b. Use of more precise data and estimation techniques in the later estimations.

4. Project Schedule:

Planning for the distribution began in early 1972. The initial Project Protocol was completed in September of that year, and preparations continued into early 1973. In April 1973 training

workshops were held for the field workers in each of the three provinces. Four six-month distribution cycles were then carried out according to the following schedule:

a. First distribution cycle: May 1973 - Oct. 1973

b. Second Distribution cycle: Nov. 1973 - April 1974

c. Third distribution Cycle: May 1974 - Oct. 1974

d. Fourth distribution cycle: Nov. 1974 - April 1975

5. <u>Distribution Staff</u>:

The focus of project operations in each kecamatan was the health center serving that kecamatan. Two health personnel were chosen from the staff of each participating health center to serve as field workers for the distribution. (During the second and third cycles three additional workers were assigned to the project, bringing the total to 43 workers.) The supervisors reported that selection of the personnel for the distribution was based primarily on two criteria: availability and previous work experience, in that order of importance.

The workers selected, all male, ranged in age from 25 to 51 years. Almost all had some form of paramedical training, and over a third had three years or more of formal training in a health discipline. Most had experience with mass health campaigns such as malaria and yaws eradication and BCG vaccination programs.

The project planners originally intended that underemployed former yaws workers be engaged as the field workers for the project. However, three-quarters of the workers for whom there is data on previous work experience had never participated in a yaws

campaign. Moreover, all but two of the 43 workers had other job responsibilities in addition to the vitamin A project. In East Java, provincial and local health authorities reported that their health personnel were fully employed before the vitamin A project began and had to be withdrawn from other duties in order to participate in the distribution.

Before the first distribution cycle began, each field worker attended a four-day workshop in his province. At the workshops instruction was given on the nature and prevention of vitamin A deficiency, and on procedures for capsule distribution and record-keeping. Following the workshops the field workers were assigned to the project on a half-time basis,* under the supervision of the physicians who administer the health centers. The field workers' other job responsibilities were generally related to communicable disease control or delivery of clinical services.

Evaluation of these workers has led to the conclusion that the qualities which are most important for effective work performance are dependability and perseverance. The experience of the pilot project suggests that training in a health discipline may not be an important criteria for effective performance.

6. Vitamin A Capsules:

The dosage administered to the target population was 200,000 IU vitamin A with 40 IU tocepheryl acetate (vitamin E) in oil. The capsules used were of a soluble gelatin type which is

*Except in East Java, where participation was usually on a quarter-time basis.

administered by cutting off a protrusion at one end and squeezing the contents into the recipient's mouth.

In general, the capsules proved satisfactory for administration to young children under field conditions. Their major disadvantage was that the oil tended to seep out of the cut end, soiling the workers' hands and causing some loss of the vitamin. During administration of the capsule the workers' hands often came into contact with the children's mouths, causing some concern about transferral of saliva from mouth to mouth. However, the capsules carry the important advantage of being relatively easy to administer to fussy children, as the oily contents are difficult for such children to spit out.

The capsules were provided to the Ministry of Health by UNICEF. No significant problems arose with respect to the shipping of the capsules from Denmark to Indonesia. However, the process of clearing them through customs in Jakarta caused some delay, and during clearance of the first shipment 4,000 capsules were lost or retained at customs.

Some difficulty in transferring capsule supplies within Indonesia was experienced, however. The first capsule shipment arrived in Indonesia before the distribution began and was allocated to the participating health centers via the Applied Nutrition Projects division of the Ministry of Health. A second capsule shipment arrived in Jakarta in July 1974 and a third in September 1974. These last two shipments, containing a combined total of 300,000 capsules, were received by UNICEF and forwarded to the

Pharmacy Department of the Ministry of Health. The Pharmacy Department in turn forwarded the capsules to the pharmacy depots of the provincial health departments. The project administrators were not informed by UNICEF of the change in channel for allocation of the capsules, and were unable to locate the capsule supplies for some months. Allocation of the capsules to the health centers was not completed until mid-January.

During this period a number of health centers ran out of capsule supplies and were forced to stop the distribution. By the beginning of November the distribution had halted in twelve kecamatans, and by December in fourteen. The distribution recommenced in all of these kecamatans during January. Altogether more than 600 worker/days were lost due to depletion of capsule supplies, and about 20,000 children did not receive capsules because of the delay. Only kecamatans in West and Central Java were affected, as East Java still maintained a large stock from the initial capsule shipment.

7. Implementation of the Distribution:

The initial distribution cycle was preceded by visits by project staff to village leaders in the project areas. The purpose of these visits was to explain the distribution and to ask the cooperation of the local authorities. Each village leader (Lurah) was requested to appoint two residents of the village to serve as guides and assistants to the field workers. These "village aides" were paid daily stipends for their participation. While in general the assistance of the aides was at least somewhat helpful,

in many cases - particularly in the urban areas - the aides proved to be neither dependable nor knowledgeable about their areas.

Both rural and urban residential areas in Java are divided into clusters of 20 - 30 households known as "RTs". These RTs formed the basic unit for the distribution of capsules. Upon entering each RT, the field workers would either have the children gathered in a central location (with the assistance of the village aides and the local authorities), or would go from house to house seeking out eligible children. Frequently a combination of the two approaches would be used, with the workers first collecting the children and then going from house to house to seek out missing children. The workers were instructed to use whatever approach seemed most appropriate to local conditions and most acceptable to local authorities. They were encouraged, however, to seek out at their homes any children missed by the collective distribution. The approach of gathering the children seemed to be more efficient, but the procedure of going from house to house reduced the likelihood of missing children who were ill, malnourished, or whose parents were unable or unwilling to take them to a central collection point.

The field workers followed similar distribution procedures in the rural and the urban areas because the pattern of clustering of households into RTs prevailed in both types of areas. However, in the rural subdistricts the population clusters tended to be scattered over wider geographical areas. The field workers covering these areas were therefore required to travel longer distances than the workers covering the more densely populated and

compact urban areas. All of the field workers traveled by means of bicycles provided by UNICEF.

During the first distribution cycle the field workers visited all of the villages in their assigned areas once. While some worked in pairs, most followed the more effecient procedure of operating independently. The workers were instructed to register by name, name of parent, sex, and age each child between the ages of 12 and 48 months. Children in that age range who were residents of a village in a project area but who were away at the time were also registered. If a child were given a capsule at the time of registration, that fact was recorded. If a child was not given a capsule because he was away, very ill, or because his parents refused the vitamin, the non-receipt and the reason were also recorded. Children judged by the workers to be ill were not given capsules in order to avoid subsequent illness or death being attributed to the capsule. A separate registration list, with the information on receipt and non-receipt of capsules, was maintained by the field worker for each RT. These records will subsequently be referred to as Form B.

At the time each child was registered an identification card (Form A) was made out for him and given to his parents. Each card was marked with a number which corresponded to a number assigned to the child on the registration list (Form B) for his RT. The cards were intended to make subsequent identification of the child easier for the workers. Their usefulness was limited, however, by a high loss rate and the time consumed in filling out new cards

During the second, third, and fourth cycles the workers revisited the villages in their areas in the same order in which they were first visited. In the areas in which capsule supplies were depleted during the third and fourth cycles, villages scheduled to be covered during the periods of depletion were not visited by the workers. When supplies were replenished the workers visited the villages scheduled to be covered at that time, rather than going back to the villages scheduled during the period of depletion. A number of villages were, therefore, visited by workers only three times during the four distribution cycles.

During each re-visit by a worker to a village, the receipt and non-receipt of a capsule by each child was recorded on Form B. Younger children became eligible to receive capsules (and were added to the list) as they reached the age of 12 months. Older children lost their eligibility when they passed the age of 48 months. In practice, precise determination of each child's age was impossible and workers tended to extend the age boundaries by including rather than excluding children of questionable age. The workers were instructed to follow-up children not dosed in previous cycles because of illness or absence, but it is not known how conscientiously this instruction was followed.

8. Toxic Reactions:

During the course of the distribution the field workers frequently encountered reports that the capsules had caused vomiting and diarrhea. As a result of these reports, there were instances in which parents refused to allow capsules to be administer-

ed to their children, or withdrew them from the presence of the field workers. Such rumors are to be expected in connection with a new medication, but concern about possible toxic effects prompted investigation by physicians of reported incidents occurring during the first two distribution cycles. In each of the cases investigated by a physician, the conslusion of the physician was that the reported illness was not related to ingestion of the vitamin. While many reports of illness were not investigated and we cannot say categorically that no toxic reactions have occurred, none have been verified. Reports and rumors of illness due to the capsules have persisted throughout the distribution, but do not appear to have significantly affected the acceptability of the capsule to the general population. They have, however, required the field workers to spend time explaining the purpose of the capsules and reassuring the parents of their safety.

C. EVALUATION

1. Data Collection:

The data which formed the basis of the evaluation was collected by means of a recordkeeping and a reporting system built into the administrative and supervisory structure of the project. This system was based on the registration lists (Form B) maintained by the field workers. Each month the data recorded by each worker on his forms were summerized into a monthly report (Form C) which was signed by the worker's supervisor and sent to the project office in Jakarta. Copies of the monthly reports were also sent to the regency physicians (Dokabu), who in turn sent summary reports

(Form D-E) to the Provincial Project Leader. The provincial summary reports (also on Form D-E) were sent by the Provinical Project Leaders to the project office in Jakarta. The reporting system is illustrated schematically in Appendix III.

Since the initiation of the project a number of changes have been made in the reporting forms and in the reporting requirements for project personnel. The changes have been almost entirely in the direction of simplification of the forms and reduction in reporting requirements. Nevertheless, even the simplified forms proved to be time-consuming and difficult for the workers to fill out correctly. The necessity of registering and subsequently identifying each individual child reduced the effeciency of the workers. While detailed recordkeeping of this type was felt to be essential to the evaluation of the pilot project, it would not seem necessary in a routine distribution. A simpler system which would minimize risk of double-dosing and require the field workers to account for their time would seem preferable. A daily record form on which the workers reported to their supervisors the specific RTs covered and the number of children dosed might prove adequate for those purposes. It is hoped that when the planned comprehensive form for the reporting of all health center activities is introduced, the reporting of vitamin A distribution will be included in that form.

The health center heads, regency physicians, and Provincial Project Leaders were requested to submit monthly reports (Form C-2) of their supervisory activities related to the project,

but such reports were infrequently submitted. The information obtained from these personnel has come primarily through site visits, interviews, and non-routine letters and reports. Direct supervision of the field workers' activities seems to have been relatively infrequent, which has made it difficult to verify adherence to appropriate procedures as well as the data contained in the monthly reports.

2. Field Surveys:

In order to provide a check on the field workers' reports, surveys were carried out in two villages in which capsules had been distributed. Both villages were surveyed after the fourth distribution cycle. One village, in West Java, was surveyed one month after capsules had been distributed there. The second village, in Central Java, was surveyed four months after distribution. The surveys were conducted by a member of the Vitamin A Project Committee and two third-year students at the Academy of Nutrition in Jakarta. The survey interviewers attempted to visit each home in the two villages, and to register all children under six years of age. The children were listed by name and age, and their parents were asked whether the children had received a capsule from the project field worker during his previous visit to the village. The names of the children listed by the survey interviewers were then cross-checked with the names on the field workers' registration lists (Form B) to determine the extent to which the two lists were in agreement.

The surveys were designed to provide a check on whether

the children reported by the field workers as having received capsules had in fact been dosed. The surveys did not succeed in fulfilling this objective, however, because of a tendency on the part of parents to report receipt of capsules by children who were unlikely to have been dosed. Most of the latter were children whom the field workers explicitly recorded as not dosed. Some were children not registered by the field worker at all. This discrepancy calls into question the validity of the reports of the parents and precludes their providing a valid check on the reports of the field workers.

3. Findings - Field Worker Efficiency:

Field worker efficiency was measured in terms of the average number of children dosed per worker/day. The averages were calculated by cycle for each province according to the following formula:

a. the total number of capsules administered during the cycle

divided by

b. the combined total of days worked during the cycle by all of the field workers in the province

Only the number of days reported as actually worked were included. Days which were scheduled for distribution but on which distribution did not take place - e.g. during periods of capsule depletion - were not counted as "days worked".

Table I shows the average numbers of children dosed per worker/day by cycle and by province. As can be seen from the table, worker efficiency declined slightly over time in West and Central

Java. In East Java worker efficiency appears to have improved over time. However, reporting of days worked has been somewhat inconsistent in that province, and the validity of the apparent increase in efficiency is therefore somewhat questionable.

TABLE I

AVERAGE NUMBER CHILDREN DOSED

PER WORKER/DAY

PROVINCE	CYCLE I	CYCLE II	CYCLE III	CYCLE IV
West Java	46	41	39	43
Central Java	34	27	28	26
East Java	22	20	*	31

* Reporting of days worked was not sufficiently complete to permit calculation of an average.

The daily coverage achieved by the field workers was somewhat lower than anticipated. Among the factors reported by the workers and supervisors as having adversely affected efficiency, the following were most frequently cited: (Not listed in order of magnitude of effect.)

a. Long distances to be traveled by bicycle, often over roads in poor condition

b. Heavy rains, which made travel difficult and parents reluctant to bring children out

c. The harvest, during which parents frequently took their children with them to the fields

d. Unreliability of the village aides

e. In some areas, lack of cooperation from local authorities and parents

f. High mobility and seasonal migration, particularly in the urban areas

g. Time consuming recordkeeping procedures (see Section C-1)

4. <u>Findings - Estimation of Distribution Coverage</u>:

Estimations, by province, of the percentages of the target population dosed during each distribution cycle are presented in Table II below. The percentages shown were calculated according to the following formula:

a. the number of capsules distributed in each province during each cycle

divided by

b. the target population estimations for each province

The target population estimations, which constitute the denominator of the formula, are described in section D and in Appendix II. For each province and for each cycle two percentages were calculated, one using as the denominator the maximum target population estimations, and one using the minimum target population estimations. In the table the percentages are presented in pairs. The percentages on the left of each pair were calculated using the maximum estimations, those on the right the minimum estimations.

TABLE II

ESTIMATED PERCENTAGES OF THE TARGET POPULATIONS DOSED

PROVINCE	CYCLE I	CYCLE II	CYCLE III	CYCLE IV
West Java	74-81	66-73	53-58	35-39
Central Java	88-96	77-84	77-85	56-61
East Java	83-91	79-87	66-73	76-83
Average, All Provinces	82-91	73-81	68-74	50-55

A marked decline over time in the estimated percentages of the target populations dosed is evident in Table II. The decline is most striking in West and Central Java, but a less dramatic decline is also evident in East Java.

The single most important fact contributing to the observed decline was the depletion of capsule supplies in West and Central Java. The following procedure was used to estimate the impact of the depletion on coverage rates during the fourth cycle:

a. The workers who had been inactivated by lack of supplies during November and December returned to the missed villages in May and June to distribute capsules.

b. The number of capsules distributed by these workers in the previously missed villages was added to the total number of capsules distributed during the fourth cycle.

c. The totals obtained in (b) were converted into coverage rates. The rates obtained by this means were 53-58% for West Java and 72-79% for Central Java.

Although the coverage rates achieved in West and Central Java during the third cycle were also slightly reduced by lack of supplies, the comparability of the third cycle rates and the rates obtained by the above procedure indicates that the apparent decline between the third and fourth cycles is attributable almost entirely to the depletion of capsule supplies.

A second factor contributing to the observed decline was inclusion during the first cycle of a substantial number of children who were over the age limit of 48 months, and who were dropped from the distribution during the second cycle. This phenomenon, which was evident in all three provinces, is estimated to account for 4 to 7% of the decline between the first and second cycles. The decline in coverage accounted for by this phenomenon reflects, however, not an actual decrease in the number of eligible children dosed, but rather stricter adherence during the second cycle to the age limits defining the target population.

A third factor which is thought to have contributed to the decline in coverage is the transition of the distribution from a new program to a routine program. During the first distribution cycle a great deal of effort and attention was focused on the project. Site visits were made by provincial and health center officials, the assistance of local officials was elicited, the interest of villagers was aroused, and considerable importance was attached to the task of registering every eligible child. As the cycles were repeated the distribution attracted less attention and became routinized. The task of distributing the capsules was in itself a fairly tedious and a not very challenging activity. It is to be expected, therefore, that the transition from a new to a routine program would be accompanied by some decline in local cooperation and in the industry of the workers.

D. PROJECT COSTS

The costs of the various components of the project are shown,

in both rupiah and U.S. dollars, in Appendix IV. (An exchange rate of Rp. 415 to the dollar was used.) The costs shown have been totaled for the duration of the project, from the planning stage in early 1972 through the completion of the fourth distribution cycle in April 1975.

The expenses of the evaluation component of the project (e.g. foreign and Indonesian evaluation personnel, data analysis, etc.) and the purchase price of the three vehicles provided by UNICEF were not included in the cost figures. These expenses were excluded because they do not reflect costs essential to the implementation of a distribution on this model.

Based on the figures presented in Appendix IV, the average cost per capsule administered was Rp. 80.5, or 19¢ U.S.

It should be borne in mind in evaluating the cost figures presented that the amounts shown are based for the most part on project funds allocated to the Eye Health Division and to the respective provinces. Since funds left unspent at the end of a fiscal year are more likely to be spent on other programs than to be returned to the treasury, we do not know precisely how much of the allocated funds were in fact spent on the distribution. The budget was originally drawn up to cover the expenses of distribution of capsules to a target population more than twice as large as that actually reached. As far as possible adjustments have been made in the calculations to allow for that discrepancy. Nevertheless, the cost figures shown in Appendix IV are inflated by the reduction in the magnitude of the population covered and by the vagaries of

the accounting system. They therefore reflect the actual cost to the government of Indonesia and UNICEF for implementation of the distribution more accurately than they reflect the necessary costs inherent in implementing a distribution on this model.

E. CONCLUSIONS AND RECOMMENDATIONS

The experience of the pilot distribution has been of value in demonstrating both the strengths of the system and its limitations. This section will present conclusions which can be drawn from the experience, and will make recommendations for future program planning.

Major conclusions include the following:

a. The 200,000 IU dosage of vitamin A with 40 IU vitamin E administered in the soluble gelatin capsule has proven acceptable to the general population and appropriate for use under field conditions.

b. The feasibility of reaching a substantial proportion of a pre-school age population was demonstrated by the experience of the first two distribution cycles.

c. The dependence of the system on administrative support - particularly with respect to capsule supplies - was indicated by the experience of the latter two cycles.

Conclusions about the effectiveness of the distribution are limited by an area of uncertainty. This area concerns the extent

to which marginal and deficient children were represented in the population which received capsules. If the dosed and undosed children were equivalent in their susceptability to vitamin A deficiency, then the results of the clinical study would indicate that hypovitaminosis A was substantially reduced in the population dosed. If, however, the two groups differ in their susceptability, we cannot determine with any certainty the extent to which hypovitaminosis A has been reduced in the target population. Lack of information about the relative susceptability of the two groups limits, therefore, the conclusions that can be drawn about the effectiveness of the distribution.

The following recommendations for future program planning are suggested by the experience of the distribution:

a. Because of the considerable cost of large-scale distribution - both in financial terms and in use of manpower - it is suggested that future distributions be focused in areas evidencing high prevalence of xerophthalmia. Timing of distributions to coincide with the apex of seasonal prevalence curves would also help to maximize impact. Identification of high prevalence areas and of seasonal patterns would require carefully done prevalence surveys and standardization of case reporting. Such efforts are felt to be sounder long-run investments than is distribution of vitamin A in areas of unknown prevalence.

b. Training in a health discipline does not seem to be an essential prerequisite for handling of massive-dose capsules. Since health personnel are in demand for progrmas in which their skills are required, it is recommended that other types of reliable personnel be utilized as capsule distributors. Becasue distribution of the capsules is a preventive health measure, it is nevertheless appropriate that the local health centers retain direction and supervision of capsule distributions.

c. The relative effectiveness of such a program will inevitably depend on the personnel involved at all levels. To assure maximum productivity and cooperation, the supervisors should be involved in the early stages of planning and the criteria for selection of personnel in each category should be specified in advance.

d. A simpler reporting system, such as is discussed in Section C-1 is suggested in order to increase the efficiency of capsule distributors.

e. It is recommended that every health center be supplied with massive-dose capsules, and that these capsules be administered to young children as an integral part of routine health care.

REFERENCES

1. Soekirman: Priorities in Dealing with Nutrition Problems in Indonesia. Cornell International Nutrition Monograph Series. No. 1, 1974.

2. Oomen HAPC: The Incidence of Xerophthalmia in Java in Relation to Age and Sex. Trop. Geogr. Med. 9: 57.

3. ten Doesschate J: Causes of Blindness in and Around Surabaja, East Java, Indonesia. Doctoral Thesis, Jakarta, 1968.

4. WHO Study Group: The Prevention of Blindness. WHO Technical Report Series. No. 518, 1973.

5. Venkataswamy G: Keratomalacia. Israel J. Med. Sci. 8:1190-1191, 1972.

6. Blankhart DM: Individual Intake of Food in Young Children in Relation to Malnutrition and Night Blindness. Trop. Geogr. Med. 19: 144-53, 1967.

7. Oomen HAPC: Vitamin A Deficiency, Xerophthalmia and Blindness. Nutr. Rev. 32:161, 1975.

8. Roels OA: The Fifth Decade of Vitamin A Research. International Symposium on Metabolic Function of Vitamin A. Amer. J. Clin. Nutr. July and August, 1969.

9. Oomen HAPC, McLaren DS, Escapini H: Epidemiology and Public Health Aspects of Hypovitaminosis A. A Global Survey. Trop. and Geogr. Med. 4:271-315, 1964.

10. WHO/SEAO: Consultation on Prevention of Xerophthalmia in South-East Asia, Hyderabad, 27-29 March, 1972. WHO Document. NUTR./72.3.

11. Swaminathan MC, Sushella TP, Thimmayama BVS: Field Prophylactic Trial with a Single Annual Oral Massive Dose of Vitamin A. Amer. J. Clin. Nutr. 23:119-122, 1970.

12. Gaffar MA: Report on vitamin A Prophylaxis Programme in Mysore State. Report to the WHO Meeting of Nutrition Experts for Consultation on Prevention of Xerophthalmia. March 17, 1972.

13. Nair NV: Report on Vitamin A Prophylaxis Programme in Kerala State. Report to the WHO Meeting of Nutrition Experts for Consultation on Prevention of Xerophthalmia. March 17, 1972.

14. Srikantia SG, Reddy V: Effect of a Single Massive Dose of Vitamin A on Serum and Liver Levels of the Vitamin. Amer. J. Clin. Nutr. 23:114-118, 1970.

15. Sommer A: Assessment of Xerophthalmia and The Mass Vitamin A Prophylaxis Program in El Salvador. American Foundation for Overseas Blind, New York, 1975.

16. Hermana: An Annotated Bibliography of Food and Nutrition Research in Indonesia. Indonesian Nutrition Research Institute, Bogor, 1971.

17. Oomen HAPC: Clinical Epidemiology of Xerophthalmia in Man. Amer. J. Clin. Nutr. 22:1098-1105, 1969.

18. Oomen HAPC: A Survey on Malignant Malnutrition in Djakarta Toddlers. Madjalah Kedokteran Indonesia. June, 1953.

19. Sinha DP, Bang FB: Seasonal Variation in Signs of Vitamin A Deficiency in Rural West Bengal Children. The Lancet, August 4, 1973, pp. 228-231.

20. McLaren DS, Oomen HAPC, Escapini H: Ocular Manifestations of Vitamin A Deficiency in Man. Bull. Wld. Hlth. Org. 34:357-361, 1966.

21. Oomen HAPC, ten Doesschate J: The Peridodicity of Xerophthalmia in South East Asia. J. Ecol. Food and Nutr. 2:207-217, 1973.

22. McLaren DS, Shirajian E, Tchalian M, Khoury G: Xerophthalmia in Jordan. Amer. J. Clin. Nutr. 17:117-130, 1965.

APPENDIX I

- Vitamin A Deficiency Prevention Pilot Project Committee
  - Deputy Project Director
    - West Java
      - Prov. Project Dir.
        - Regency Physician (1)
          - Supervisors (2)
            - Field Workers (8)
    - Central Java
      - Prov. Project Dir.
        - Regency Physician (1)
          - Supervisors (4)
            - Field Workers (25)
    - East Java
      - Prov. Project Dir.
        - Municipality Physician (1)
          Regency Physician (1)
          - Supervisors (4)
            - Field Workers (10)

APPENDIX II

METHODOLOGY FOR CALCULATION OF TARGET POPULATION ESTIMATES

A. MINIMUM ESTIMATES

1. West Java:

   a. The total population figures for each of the four project kecamatans in West Java were taken from the 1971 census publication "Population By Subdistrict in Java-Madura", Preliminary Figures Series B, No. 2.

   b. The ratio of the population in the age interval 1-3 years (12-48 months) to the total population in West Java was calculated from the single-year-of-age data obtained by the 1971 Sample Population Census. This ratio for West Java was .1116.

   c. The four total population figures obtained in Step (1) were each multiplied by the ratio .1116 to yield an estimate of the population aged 12-48 months in each of those kecamatans in 1971.

   d. The population in each kecamatan was assumed to have experienced a growth rate of 1.9% in each year since the 1971 census. The figure 1.9% is the estimated average annual growth rate experienced by the population of Java in the decade 1961-71. (G. McNicoll and Si Gde Made Mamas, "The Demographic Situation in Indonesia", Papers of the East-West Population Institute, NO. 28, December 1973, Honolulu, Hawaii, U.S.A.) Therefore in order to adjust the estimates for two

years growth in the period 1971-73, each of the four estimates obtained in Step (3) was multiplied by 1.0192. The products so obtained constitute our minimum estimates for the four project kecamatans in West Java, for the first two distribution cycles (May 1973 - April 1974).

e. To obtain estimates for the third and fourth distribution cycles, conducted during the period May 1974 - April 1975, the estimates obtained in Step (4) above were multiplied by 1.019. This adjustment was made to account for growth of the population during the first year of the distribution.

2. Central Java:

a. The procedures used to calculate the minimum estimates for the eleven project kecamatans in Central Java were identical with those described above for West Java, with two exceptions:

1. The ratio of the age interval 1-3 to the total population in Central Java was calculated to be .0977.
2. Some of the target-age population in two of the kecamatans (Susukan and Tengaran) were included in the vitamin A clinical study. The clinical study population in those two kecamatans was subtracted from the total target age group in those kecamatans, since they were not included in the distribution.

3. <u>East Java</u>:

The procedures followed to obtain the minimum estimates for East Java differed from those used for West and Central Java in two major respects:

1. The basis of the estimates for the kecamatans in East Java was the ratio of the population aged 1-3 to the population aged 0-4, rather than the ratio of 1-3 to the total population which was used for West and Central Java. The former ratio provides a slightly more precise estimate than does the latter because it negates to a greater extent the effect of under-enumeration in the age interval 0-1. The more precise ratio was not used for West and Central Java because of unavailability of the necessary data.

2. Because the distribution areas in East Java consisted of selected desas rather than entire kecamatans, the census data on which the estimates were based were obtained for each of the selected desas (villages). (Step 1 below). The census data from all the selected desas were then summed and the estimates calculated for the total project areas within each kecamatan. It should be borne in mind, therefore, that the estimated target populations presented in the attached table represent the estimated

target populations in the selected desas (approximately 10 in each kecamatan), rather than in the entire kecamatans as is the case in the other two provinces.

b. The procedures used to obtain the minimum estimates for East Java were as follows:

1. The 1971 Population Census figures for the population in the age interval 0-4 were obtained for each desa included in the distribution.
2. The figures obtained in Step (1) were summed by kecamatan.
3. The ratio 1-3 to 0-4 was calculated from the 1971 Sample Population Census to be .642 for East Java. This ratio was multiplied by the figure obtained for each kecamatan in Step (2), yielding an estimate of the population aged 1-3 in the selected areas within each kecamatan in 1971.
4. To adjust for population growth in the interval 1971-73, each of the kecamatan estimates obtained in Step (3) was multiplied by 1.0192. The products so obtained constitute our minimum estimates for the East Java distribution areas during the first two distribution cycles (May 1973 - April 1974).
5. The estimates obtained in Step (4) were multiplied by 1.019 to account for population

growth during the period May 1973 - April 1974, and therefore to obtain estimates of the target populations during the third and fourth cycles (May 1974 - April 1975).

B. MAXIMUM ESTIMATES

International experience with census data has indicated that censuses underenumerate all age groups of the population, and that infancy and early childhood age groups tend to be more severely underenumerated than older age groups. In order to obtain a professional estimate of the degree of underenumeration reflected in the census data relating to the target population age interval, Dr. Peter MacDonald of the Lembaga Demografi Fakultas Ekonomi, Universitas Indonesia, was consulted. Dr. MacDonald's analysis of the 1971 census data for Java has indicated that the most severe underenumeration occurred in the age interval 0-1, and that under an assumption of no fertility decline in the five years preceding the census, underenumeration in the age interval 0-4 would be less than 10%. (Perkiraan Tingkat Fertilitas dan Mortalitas untuk setiap Daerah di Indonesia, Table B: "Penduduk Jawa dan Madura Menurut Umur dan Jenis Kelamin 1971", Lembaga Demografi, Fakultas Ekonomi, Universitas Indonesia, Oktober 1973).

As Dr. MacDonald's analysis suggests that a fertility decline has occurred and is reflected in the census data, his considered opinion was that "underenumeration in the age interval 1-3 is certainly under 10% and is almost certainly under 5%." (Personal communication.)

In calculating maximum estimates for the target population our

intention was to define an upper limit for the estimate interval which would give us a reasonable certainty that the true population size would lie somewhere within the interval. We therefore chose to base our maximum estimates on the conservative assumption that undercounting in the census figures for our target age group may have approached, but did not exceed, 10%.

The maximum estimates for each kecamatan were therefore obtained by multiplying each minimum estimate by 1.10.

C. A NOTE ON INTERPRETATION

The minimum and maximum estimates calculated by the above procedures were used to estimate the proportion of the target population dosed by the field workers in each kecamatan. In interpreting the proportions so obtained, it should be noted that variation in the estimated proportions dosed may reflect factors other than the thoroughness of the workers, such as the following:

a. Variation between kecamatans in the ratio of the age interval 1-3 to the total population (or in the case of East Java, the ratio of the age interval 1-3 to the interval 1-4).

b. Variation between kecamatans in annual growth rate.

c. Seasonal variation of population size within a kecamatan due to seasonal migration.

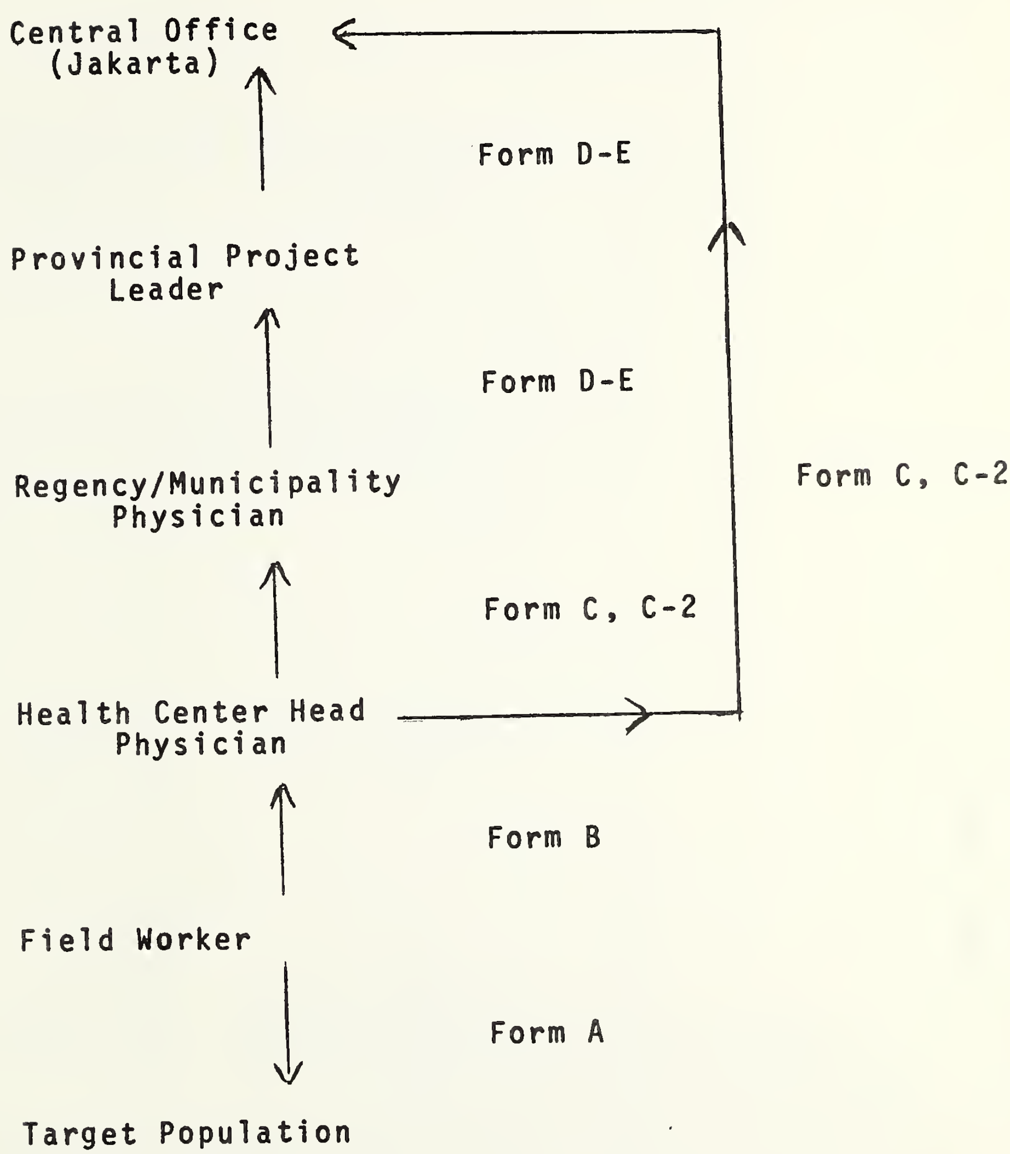
TARGET POPULATION ESTIMATES

PROVINCE	KABUPATEN	KECAMATAN	TARGET POPULATION			
			Minimum Estimate		Maximum Estimate	
			1973/4	1974/5	1973/4	1974/5
West Java	Sumedang	Cikeruh	6,473	6,596	7,120	7,255
		Situraja	4,823	4,915	5,305	5,406
	Karawang	Cilamaya	10,363	10,560	11,399	11,616
		Jatisari	10,402	10,600	11,442	11,659
		Total:	32,061	32,671	35,266	35,936
Central Java	Semarang	Bringin	5,265	5,365	5,792	5,902
		Tuntang	4,872	4,965	5,359	5,461
		Salatiga	3,631	3,700	3,994	4,070
		Jambu	3,296	3,359	3,625	3,694
		Bawen	3,412	3,477	3,753	3,824
		Susukan*	5,948	6,061	6,542	6,666
		Suruh	4,972	5,066	5,469	5,573
		Tengaran*	3,745	3,816	4,120	4,198
		Ungaran	6,137	6,254	6,751	6,879
		Gunung Pati	3,072	3,130	3,379	3,443
		Klepu	6,957	7,089	7,653	7,798
		Total	51,307	52,282	56,437	57,508
East Java	Lamongan	Babat	1,805	1,839	1,985	2,023
		Kembang Bahu	1,529	1,558	1,681	1,713
		Tikung	1,615	1,646	1,776	1,810
	Surabaya	Tambaksari	1,838	1,873	2,022	2,060
		Tandes	2,092	2,132	2,301	2,345
		Total	8,879	9,048	9,765	9,951
	GRAND TOTAL:		92,247	94,001	101,468	103,395

* Adjusted by subtraction of the population in the clinical study areas.

APPENDIX III

RECORDKEEPING AND REPORTING SYSTEM



APPENDIX IV

PROJECT OPERATIONAL COSTS: 1972 - 75*

GOI Costs	Central Administration		Provincial Costs		Totals	
	Rupiah	Dollars	Rupiah	Dollars	Rupiah	Dollars
A. Incentives	1,824,000	$ 4,395	8,548,000	$20,598	10,372,000	$24,993
B. Supplies	2,800,000	6,747	770,000	1,855	3,570,000	8,602
C. Equipment	-	-	250,000	602	250,000	602
D. Handling	350,000	843	945,000	2,277	1,295,000	3,120
E. Travel	850,000	2,048	922,000	2,222	1,772,000	4,270
F. Miscellaneous	1,400,000	3,373	918,000	2,212	2,318,000	5,585
G. GOI Totals	7,224,000	$17,406	12,353,000	$29,766	19,577,000	$47,172
UNICEF COSTS						
A. 40 Bicycles for field workers					830,000	$ 2,000
B. Purchase and shipment of capsules					2,131,000	5,134
C. UNICEF Total					2,961,000	7,134
GRAND TOTALS					22,538,000	$54,306

*Exchange rate used: Rp 415 = $1 U.S.

AN EVALUATION OF THE VITAMIN A DEFICIENCY PREVENTION PILOT PROJECT IN INDONESIA, 1973-1975. (1975)

Date Due

Reference		Copy	